FEB 2 8 2012

510 (k) summary

5. 1 Submitter

Synexmed (Shenzhen) company limited
B-11/F, ZTY Building, Taohua Road, Futian Free Trade Zone
Shenzhen, 518038, China
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Establishment Registration Number: 3008388400

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5.2 Device

Trade name: E-Pass ™
Classification Name: Cardiopulmonary Bypass Adaptor, Stopcock, Manifold or Fitting
Classification: Class II
Common Name: Hemostatic Valve
Regulation Number: 870.4290

5.3 Predicate Device

The predicate devices used to determine substantial equivalence for the EasyPass Y-connector Hemostatic Valve marketed by Millimed A/S (#K042060).

5.4 Device Description

The E-Pass is a unique one-hand operated, "push-pull" hemostatic valve system. It consists of two pieces of silicone hemostasis valve. The quick open-close valve reduces the patient blood loss significantly during endovascular procedures. In the push forward position the valves is 100% open for safe insertion and removal of devices. In the pulled back position the valve is 100% closed and seals smoothly around the inserted devices. Once the valve is closed, devices can still be manipulated freely. E-Pass eliminates the need for rotating hemostatic valve adjustments during the procedure. The E-Pass hemostatic valve system is compatible with most interventional devices based on rapid exchanged and over-the-wire technology. There are three models of the E-Pass: the standard

E-Pass and the E-Pass20/E-Pass50. The configuration of the sideport is the only difference among the three models. The sideport of the standard E-Pass ends in a female luer, while the sidearm of the E-Pass 20/ 50ends with a 20/50 cm extension tubing and 3-way stopcock.

5.5 Intended Use

The E-Pass™ Hemostasis Valve is intended to maintain hemostasis during the introduction/withdrawal and use of diagnostic and interventional devices up to an external diameter of 7 French.

The guide wire insertion tool helps the guide wire go through the hemostasis valve to reach the guiding catheter.

The torquer provides a handle for easier manipulation of the guide wire when inserted into the proximal end of the guide wire.

5.6 Comparison of Characteristics

Comparisons of the proposed and predicate devices show that the technological characteristics such as materials, performance characteristics, and sterilization are identical or substantially equivalent to the currently marketed predicate devices.

5.7 Performance Data

The results of the performance testing demonstrated the safety and effectiveness of the E-Pass ™ Hemostatic Valve.

Performance testing mainly includes the following tests:

- **Visual Inspection for Pouch Integrity**
- **Pouch Peel Test**
- **E-Pass Visual Inspection**
- **Leak Test without products inserted**
- **E-Pass Alarm pressure leak rate**
- **Tensile test on assembly of Extention tube/Y-hub**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 2 8 2012

Synexmed Shenzhen Company Limited
c/o Ms. Ada Ho
Regulatory Assistant
B-11/F, ZTY Bldg, Taohua Road, Futian
Free Trade Zone
Shenzhen, Guangdong 518038
China

Re: K113148
Trade/Device Name: E-Pass™ Hemostasis Valve
Regulation Number: 21 CFR 870.4290
Regulation Name: Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting
Regulatory Class: Class II
Product Code: DTL, DQX
Dated: October 8, 2011
Received: October 24, 2011

Dear Ms. Ho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M. J. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113148

Indications for Use

510(k) Number (if known): K113148

Device Name: E-Pass™

Indications For Use:

The E-Pass is intended to maintain hemostasis during the introduction/withdrawal and use of diagnostic and interventional devices up to an external diameter of 7 French.

The guide wire insertion tool helps the guide wire go through the hemostasis valve to reach the guiding catheter.

The torquer provides a handle for easier manipulation of the guide wire when inserted into the proximal end of the guide wire.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. A. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113148